REMARKS

I. Petition for Extension of Time

Applicants herewith petition the Commissioner for Patents to extend the time for response to the Office action mailed September 21, 2005 for three months from December 21, 2005 to March 21, 2006. Authorization is given to charge the extension of time fee of $1,020.00 (37 C.F.R. §§1.136 and 1.17) to Deposit Account No. 23-1703. Any deficiency or overpayment should be charged or credited to the above numbered deposit account.

II. Claim Amendments

Claim 1 has been amended to clarify the structural arrangement of the active ingredients within the claimed tablet formulation. Specifically, the tablet formulation comprises two actives: a proton pump inhibitor and at least one non-steroidal anti-inflammatory drug (NSAID). The proton inhibitor is protected by an enteric coating layer. Advantageously, the acid-susceptible proton pump inhibitor is separated within the tablet formulation from the NSAID by the enteric coating layer protecting the proton pump inhibitor.

The claim amendment is fully supported by the specification and figures as originally filed. As such, no new matter has been introduced by the claim amendments.

III. Claim Rejection – Double Patenting

Claims 1, 4-14, 23-28, 32-34 and 37-45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of US 6,365,184 (the "'184 patent"). A Terminal Disclaimer with respect to the '184 patent was filed May 19, 2004. Withdrawal of the rejection is requested.

IV. Claim Rejection – 35 U.S.C. §103

Claims 1, 4-14, 23-28, 32-34 and 37-45 are rejected under 35 U.S.C. §103(a) as being unpatentable over US 4,786,505 to Lovgren et al. (the "'505 patent") in view of EP 0 426 479 ("EP").

A. The '505 patent discloses an enteric coated core comprising a mixture of a proton pump inhibitor and other pharmaceutically acceptable substances.

The '505 patent discloses and claims an oral pharmaceutical preparation comprising a core, a subcoating layer and an enteric coating layer (claim 1). The core comprises omeprazole mixed with an alkaline reacting compound and other pharmaceutically acceptable excipients (col. 3, lines 37-65). Thus, it is not just the proton pump inhibitor which is protected by the enteric coating. Rather, all of the materials in admixture within the core, i.e., omeprazole, the alkaline reacting compound and excipients, are protected by the subcoating layer and enteric coating layer.

B. The core material of EP is a mixture comprising omeprazole, a NSAID and pharmaceutically acceptable excipients.

It is acknowledged by the Examiner that the '505 patent does not disclose a combination of a proton pump inhibitor and a NSAID.

Rather, EP discloses a pharmaceutical composition in an oral tablet form consisting of a NSAID and omeprazole. Specifically, in accordance with Example 12 of EP (col. 9), the pharmaceutical composition in tablet form comprises a NSAID component in combination with omeprazole and other auxiliary agents. Thus, when taken alone, EP suggests a core material comprising a combination or mixture of a NSAID, omeprazole and pharmaceutically acceptable excipients. As such, there is no meaningful suggestion of any specific arrangement of ingredients within the tablet itself.

Furthermore, EP does not show an enteric coating layer. At col. 7, lines 49-50, EP discloses that "[v]arious conventional techniques for preparing medicament tablets or caplets can be employed". However, by itself, this disclosure does not suggest that the components of the mixture, the NSAID and omeprazole, are physically separated from each other by an enteric coating layer. Rather, EP suggests that the NSAID and omeprazole are physically combined to form a tablet. Without the advantage of hindsight, no meaningful suggestion can be gleaned from EP for separating the NSAID and omeprazole by an enteric coating layer.

C. The combination of the '505 patent and EP suggests an enteric coated core containing a mixture of omeprazole, a NSAID and excipients.

The enteric-coated core of the '505 patent is a combination of omeprazole and pharmaceutically acceptable substances. In contrast, EP discloses a tablet core containing a mixture of omeprazole, a NSAID and excipients, but there is no disclosure of an enteric coating covering the tablet or any of the ingredients. Therefore, it is submitted that the combination of the '505 patent and EP suggests an enteric coated core comprising a combination or mixture of a proton pump inhibitor and a NSAID. Such a product does not suggest the claimed invention wherein the NSAID is separated from the proton pump inhibitor by an enteric coating layer protecting the proton pump inhibitor.

Advantageously, due to the arrangement of separate components within the claimed dosage form, it is possible to combine two active substances which are not necessarily compatible in a single dosage form. The first active substance is an acid-susceptible proton pump inhibitor that is prone to degradation in an acid reacting media. The second active substance, a NSAID, is most frequently an acidic compound. Thus, it is a significant benefit of the claimed invention that the acid-susceptible proton pump inhibitor is protected by an enteric coating layer from contact with an acidic NSAID compound. Consequently, it is possible to combine incompatible drug therapies in a single dosage form and avoid gastrointestinal side effects associated with the treatment of NSAIDs.

For all of the foregoing reasons, Applicants respectfully submit that the claimed tablet formulation and the structural arrangement of actives therein are not suggested by the combination of cited references.

Withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

CONCLUSION

Applicants submit that pending claims 1, 4-14, 22, 25-28, 33, 34 and 37-45 are in condition for allowance, which action is earnestly solicited. The Assistant Commissioner is hereby authorized to charge Deposit Account No. 23-1703 in the event that any fee is required in connection with this communication.

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Respectfully submitted,

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